

**AMENDMENTS TO THE SPECIFICATION:**

**Please amend the paragraph immediately following the heading "Cross-References to Related Applications" on page 1 (as amended by the Preliminary Amendment of February 18, 2004), as follows:**

This application is a continuation of ~~pending~~ US Patent Application Serial No. 10/114,675 filed April 2, 2002, now abandoned, which is a continuation of US Patent Application Serial No. 09/484,354 filed January 18, 2000, now US Patent No. 6,371,988, which is a divisional of US Patent Application Serial No. 08/740,031 filed October 23, 1996, now abandoned, which is a continuation-in-part of pending U.S. Patent Application Serial No. 08/603,676 filed February 20, 1996, now US Patent No. 6,423,095, which is a continuation-in-part of U.S. Patent Application Serial No. 08/543,563 filed October 16, 1995 now abandoned, all of which are incorporated by reference in their entirety.

**Please amend the paragraph beginning at page 5, line 1, as follows:**

Bone dowels having greater biomechanical properties have been produced and marketed by the University of Florida Tissue Bank, Inc., 1 Progress Boulevard, P.O. Box 31, S. Wing, Alachua, Florida 32615. Unicortical dowels from allogenic femoral or tibial condyles are available. The University of Florida has also developed a diaphysial cortical dowel having superior mechanical properties. This dowel also provides the further advantage of having a naturally preformed cavity formed by the existing ~~medullary~~ medullary canal of the donor long bone. The cavity can be packed with osteogenic materials such as bone or bioceramic.

**Please amend the paragraph beginning at page 8, line 14, as follows:**

FIG. 7 is a ~~side-elevation~~ perspective view of another dowel provided by this invention.

**Please amend the paragraph beginning at page 9, line 4, as follows:**

FIG. 22 is a ~~side-elevation~~ perspective view of a guide protector.

**Please amend the paragraph beginning at page 9, line 29, as follows:**

FIG. 37 depicts a ~~side-elevational~~ perspective view of an implanting tool.

**Please amend the paragraph beginning at page 10, line 1, as follows:**

FIG. 41 is a ~~top-elevational~~ perspective view of another embodiment of the spacer having blades.

**Please amend the paragraph beginning at page 10, line 5, as follows:**

FIG. 43 is a ~~side-elevational~~ perspective view of an autograft ~~erøek~~ Crock dowel.

**Please amend the paragraph beginning at page 10, line 7, as follows:**

FIG. 44 is a ~~side-elevational~~ perspective view of an autograft tricortical dowel.

**Please amend the paragraph beginning at page 10, line 9, as follows:**

FIG. 45 is a ~~side-elevational~~ perspective view of an autograft button dowel.

**Please amend the paragraph beginning at page 10, line 11, as follows:**

FIG. 46 is a ~~side-elevational~~ perspective view of a hybrid autograft button/allograft ~~erøek~~ Crock dowel.

**Please amend the paragraph beginning at page 10, line 31, as follows:**

FIG. 55 compares the compressive strength of ~~the~~ a load bearing member of this invention to fusion cages.

**Please amend the paragraph beginning at page 14, line 10, as follows:**

In one specific embodiment depicted in FIG. 1, the load bearing member of the spacer 10 is a bone dowel 11 soaked with an effective amount of an osteogenic composition to stimulate osteoinduction. Preferably, the osteogenic composition includes a substantially pure osteogenic factor in a pharmaceutically acceptable carrier. The dowel 10 includes a wall 12 sized for engagement within the intervertebral space IVS to maintain the space IVS. The wall 12 defines an outer engaging surface 13 for contacting the adjacent vertebrae. The wall 12 is preferably ~~cylindrically~~ cylindrical so that the bone dowel 10 has a diameter d which is larger than the height h of the space IVS between

adjacent vertebrae V or the height of the space between the lowest lumbar vertebrae L5 and the sacrum S as depicted in FIG. 2.

**Please amend the paragraph beginning at page 18, line 27, as follows:**

The spacers of this invention can also be inserted using laproscopic technology as described in Sofamor Danek USA's ~~Laproscope~~ Laparoscopic Bone Dowel Surgical Technique, © 1995, 1800 Pyramid Place, Memphis, Tennessee 38132, 1-800-933-2635. Devices of this invention can be conveniently incorporated into Sofamor Danek's ~~laproscope~~ laparoscopic bone dowel system that facilitates anterior interbody fusions with an approach that is much less ~~surgical-surgically~~ morbid than the standard open anterior retroperitoneal approaches. This system includes templates, trephines, dilators, reamers, ports and other devices required for ~~laproscope-laparoscopic~~ dowel insertion.

**Please amend the paragraph beginning at page 24, line 5, as follows:**

Alternatively, the spacers of this invention may be provided with a tool engaging hole for insertion of a tool, such as the tool depicted in FIG. 9. According to another specific embodiment depicted in FIGS. 35 and 36, the spacer 170 includes an anterior wall 171 defining a tool engaging hole 174. In a most preferred embodiment, the tool engaging hole 174 is threaded for receiving a threaded implanting tool such as depicted in FIG. 37. The inserter 220 includes a handle portion 221 with knurlings or other suitable patterns to enhance manual gripping of the handle. A shaft 222 extends from the handle 221. The distal end 223 of the shaft 222 includes a tip 225 which mates with the tool engaging hole 174. Preferably the tip 225 and tool engaging hole 174 have corresponding mating threads 226, 178. Where the tool engaging hole 174 is defined in a curved wall as shown in FIG. 35, the distal end 223 of the shaft 222 preferably includes a curved portion 224 (not shown) that conforms to the curved anterior surface of the spacer. The inserter 220 also preferably includes a T-handle 228 for spacer control and positioning. Preferably the inserter 120 includes means for rotating the threaded tip 225. In FIG. 37, the knob 230 is engaged to the tip 225 via an inner shaft extending through an

internal bore (not shown) in the handle 221 and shaft 222. The tip 225 is preferably at the end of the inner shaft with the inner shaft rotatably mounted within the handle 221 and shaft 222.

**Please amend the paragraph beginning at page 28, line 13, as follows:**

For packing the chambers of the spacers of the present invention, the carriers are preferably provided as a sponge 58,30 which can be compressed into the chamber 55 (FIG. 25) or 25 (FIG. 47) or as strips or sheets 31 which may be folded to conform to the chamber as shown in FIG. 48. Preferably, the carrier has a width and length which are each slightly greater than the width and length of the chamber. In the most preferred embodiments, the carrier is soaked with a rhBMP-2 solution and then compressed into the chamber. As shown in FIG. 47, the sponge 30 is held within the chamber 25 by the compressive forces provided by the sponge 30 against the wall 22 of the dowel 21. It may be preferable for the carrier to extend out of the openings of the chamber to facilitate contact of the osteogenic composition with the highly vascularized tissue surrounding the fusion site. The carrier can also be provided in several strips sized to fit within the chamber. The strips can be placed one against another to fill the interior. As with the folded sheet, the strips can be arranged within the spacer in several orientations. Preferably, the osteogenic material, whether provided in a sponge, a single folded sheet or in several overlapping strips, has a length corresponding to the length and width of the chamber.

**Please amend the paragraph beginning at page 29, line 17, as follows:**

In a preferred embodiment, an osteogenic composition is provided to the pores of the load bearing member. The bone growth inducing composition can be introduced into the pores in any suitable manner. For example, the composition may be injected into the pores of the graft. In other embodiments, the composition is dripped onto the graft or the graft is soaked in a solution containing an effective amount of the composition to stimulate osteoinduction. In either case the pores are exposed to the composition for a

period of time sufficient to allow the liquid to ~~thoroughly~~ thoroughly soak the graft. The osteogenic factor, preferably a BMP, may be provided in freeze-dried form and reconstituted in a pharmaceutically acceptable liquid or gel carrier such as sterile water, physiological saline or any other suitable carrier. The carrier may be any suitable medium capable of delivering the proteins to the spacer. Preferably the medium is supplemented with a buffer solution as is known in the art. In one specific embodiment of the invention, rhBMP-2 is suspended or admixed in a carrier, such as water, saline, liquid collagen or injectable BCP. The BMP solution can be dripped into the graft or the graft can be immersed in a suitable quantity of the liquid. In a most preferred embodiment, BMP is applied to the pores of the graft and then lyophilized or freeze-dried. The graft-BMP composition can then be frozen for storage and transport.

**Please amend the paragraph beginning at page 32, line 10, as follows:**

First, the carriage is manually pulled back and locked in place with a set pin. Second, the graft is loaded into the vice and is aligned with the cutter. Third, the machine is started and the RPM is set, by using a knob on the valve control. Fourth, the set pin, ~~which~~ allows the graft to be loaded onto the cutter to cut the dowel. Once the cutter has cut all the way through the graft the carriage will stop on a set pin. Fifth, sterile water is used to eject the dowel out of the cutter. It is fully autoclavable and has a stainless steel vice and/or clamping fixture to hold grafts for cutting dowels. The graft can be positioned to within ~~0.001"~~ one thousandth of an inch (0.001") which creates dowel uniformity during the cutting process.

**Please amend the paragraph beginning at page 33, line 1, as follows:**

The marrow was then removed from the medullary canal of the dowel and the cavity cleaned to create ~~of a~~ a chamber. The final machined product may be stored, frozen or freeze-dried and vacuum sealed for later use.

**Please amend the paragraph beginning at page 33, line 19, as follows:**

A vial containing 4.0 mg of ~~lyophilized~~ lyophilized rhBMP-2 (Genetics Institute) is constituted with 1 mL sterile water (Abbott Laboratories) for injection to obtain a 4.0 mg/mL solution is follows:

**Please amend the paragraph beginning at page 33, line 23, as follows:**

1. Using a 3-cc syringe and 22G needle, slowly inject 1.0 mL sterile water for injection into the vial containing ~~lyophilized~~ lyophilized rhBMP-2.

**Please amend the paragraph beginning at page 34, line 20, as follows:**

A vial containing 4.0 mg of ~~lyophilized~~ lyophilized rhBMP-2 (Genetics Institute) is constituted with 1 mL sterile water (Abbott Laboratories) for injection to obtain a 4.0 mg/mL solution as follows:

**Please amend the paragraph beginning at page 34, line 24, as follows:**

1. Using a 3-cc syringe and 22G needle, slowly inject 1.0 mL sterile water for injection into the vial containing ~~lyophilized~~ lyophilized rhBMP-2.

**Please amend the paragraph beginning at page 36, line 5, as follows:**

A vial containing 4.0 mg of ~~lyophilized~~ lyophilized rhBMP-2 (Genetics Institute) is constituted with 1 mL sterile water (Abbott Laboratories) for injection to obtain a 4.0 mg/mL solution as follows:

**Please amend the paragraph beginning at page 36, line 9, as follows:**

1. Using a 3-cc syringe and 22G needle, slowly inject 1.0 mL sterile water for injection into the vial containing ~~lyophilized~~ lyophilized rhBMP-2.